

WHAT IS CLAIMED IS:

5 1. A process for stabilizing a blood protein solution comprising:

- (a) providing a blood protein solution;
- (b) adding to the solution hydroxypropyl- α -cyclodextrin in an amount sufficient to form a stable complex with the protein; and
- (c) lyophilizing the solution of step (b) to form a lyophilized

10 protein/hydroxypropyl- α -cyclodextrin complex.

2. The process according to claim 1, further comprising reconstituting the lyophilized protein/hydroxypropyl- α -cyclodextrin complex.

15 3. The process according to claim 1, further comprising heating the blood protein solution, before or after adding hydroxypropyl- α -cyclodextrin, at least about 60°C for a time sufficient to inactivate any viruses present in the protein/hydroxypropyl- α -cyclodextrin complex.

20 4. The process according to claim 3 wherein the blood protein solution is heated for at least about 10 hours.

25 5. The process according to claim 3 wherein the blood protein solution is heated to a temperature of at least about 80°C for at least about 72 hours.

6. The process according to claim 3 wherein the blood protein solution is heated to about 100°C for at least about 1 hour.

30 7. The process according to claim 1, further comprising subjecting the blood protein solution, before or after adding the hydroxypropyl- α -cyclodextrin, to a solvent detergent viral inactivation step.

8. The process according to claim 1, wherein the hydroxypropyl- α -cyclodextrin is present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

9. The process according to claim 1, wherein the hydroxypropyl- α -cyclodextrin is present in the protein solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

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10 10. The process according to claim 2, wherein the protein is present in the reconstituted protein/hydroxypropyl- α -cyclodextrin complex in an amount greater than about 0.1% wt/vol.

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11. The process according to claim 2 wherein the protein is present in the reconstituted protein /hydroxypropyl- α -cyclodextrin complex in an amount from about 1% to about 8 %.

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12. The process according to claim 1 wherein the protein is selected from the group consisting of albumin, Factor II, Factor VII, Factor VIII, Factor IX, Factors X and X_a, fibrinogen, antithrombin III, transferrin, haptoglobin, gamma globulins, fibronectin, protein C, protein S, thrombin and C1-inhibitor.

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13. The process according to claim 1, wherein the protein is fibrinogen.

25 14. The process according to claim 12, wherein the hydroxypropyl- α -cyclodextrin is present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

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15. The process according to claim 12, wherein the hydroxypropyl- α -cyclodextrin is present in the protein solution in an amount ranging from about 2% wt/vol. to about 12% wt/vol.

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16. The process according to claim 12, wherein the fibrinogen is present in the reconstituted protein/hydroxypropyl- α -cyclodextrin complex in an amount greater than about 1% wt/vol.

35 17. The process according to claim 12, wherein the protein is fibrinogen, and the fibrinogen is present in the reconstituted protein /hydroxypropyl- α -cyclodextrin complex in an amount from about 3% wt/vol. to about 10% wt/vol.

18. A process for stabilizing a fibrinogen solution comprising:

- (a) providing a fibrinogen solution;
- (b) adding to the solution hydroxypropyl- α -cyclodextrin in an amount sufficient to form a stable complex with the protein;
- (c) lyophilizing the solution of step (b) to form a lyophilized fibrinogen/hydroxypropyl- α -cyclodextrin complex; and
- (d) reconstituting the lyophilized fibrinogen/hydroxypropyl- α -cyclodextrin complex.

19. A lyophilized blood protein/hydroxypropyl- α -cyclodextrin complex prepared by:

- (a) providing a blood protein solution;
- (b) adding to the solution hydroxypropyl- α -cyclodextrin in an amount sufficient to form a stable complex with the protein; and
- (c) lyophilizing the solution of step (b) to form the lyophilized blood protein/hydroxypropyl- α -cyclodextrin complex.

20. A blood protein product prepared by:

- (a) providing a blood protein solution;
- (b) adding to the solution hydroxypropyl- α -cyclodextrin in an amount sufficient to form a stable complex with the protein;
- (c) lyophilizing the solution of step (b) to form a lyophilized protein/hydroxypropyl- α -cyclodextrin complex; and
- (d) reconstituting the lyophilized protein/hydroxypropyl- α -cyclodextrin complex.

21. A fibrinogen product prepared by:

- (a) providing a fibrinogen solution;
- (b) adding to the solution hydroxypropyl- α -cyclodextrin in an amount sufficient to form a stable complex with the protein;
- (c) lyophilizing the solution of step (b) to form a lyophilized fibrinogen/hydroxypropyl- α -cyclodextrin complex; and
- (d) reconstituting the lyophilized fibrinogen/hydroxypropyl- α -cyclodextrin complex.

22. A blood protein product comprising a lyophilized solution of a stable complex of protein and hydroxypropyl- α -cyclodextrin.

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23. The product according to claim 22, wherein the hydroxypropyl- α -cyclodextrin is present in the solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

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24. The product according to claim 22, wherein the hydroxypropyl- α -cyclodextrin is present in the solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

25. The product according to claim 22, wherein the blood protein is fibrinogen.

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26. A stabilized blood protein solution comprising a complex of the blood protein and hydroxypropyl- α -cyclodextrin.

27. The solution according to claim 26, wherein the protein is present in the complex in an amount greater than about 3% wt/vol.

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28. The product according to claim 26, wherein the hydroxypropyl- α -cyclodextrin is present in the solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

29. The process according to claim 26, wherein the hydroxypropyl- α -cyclodextrin is present in the solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

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30. The product according to claim 26, wherein the blood protein is fibrinogen.

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